

REMARKS

1. In response to the Office Action mailed October 9, 2007, Applicant respectfully requests reconsideration. Claims 1, 2, 4-9, 14, 20-24, 27-28, 30-31, and 89-115 were last presented for examination. In the outstanding Office Action, claims 1, 2, 4-9, 14, 20-24, 27-28, 30-31, and 89-115 were rejected. No claims were allowed or objected to. By the foregoing Amendments, claims 1, 2 and 95 were amended. No claims have been canceled or added. Thus, upon entry of this paper, claims 1, 2, 4-9, 14, 20-24, 27-28, 30-31, and 89-115 remain pending in this application. Claim 1, 93 and 108 are independent claims.

2. Based upon the above Amendments and following Remarks, Applicant respectfully requests that all outstanding rejections be reconsidered and withdrawn.

Claim Rejections Under 35 U.S.C. §§ 102 and 103

3. Claims 1-2, 4, 7-9, 14, 20, 24, 27-28, 30-31, 89-93, 98-100, 104-110 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Pub. No. 2002/0019669 to Berrang (hereinafter “Berrang”) or, in the alternative, under 35 U.S.C. § 103(a) as being obvious over Berrang. Applicant respectfully requests that these rejections be reconsidered and withdrawn.

Independent Claim 1

4. Independent claim 1 recites, among other things, an implantable device for mounting to a patient’s bone comprising, at least one protuberance configured to osseointegrate with the patient’s bone without manual assistance, wherein said protuberance extends from said outer surface of said housing, the protuberance configured to separate at least a portion of said outer surface of said housing from the patient’s bone when said housing is positioned adjacent the patient’s bone prior to osseointegration.

5. Berrang discloses a cochlear prosthesis having a housing that “can be conveniently ...attached to the underlying bone with...titanium screws.” ¶[0022]. However, Berrang fails to disclose or render obvious a protuberance that is configured to osseointegrate without manual assistance and separate at least a portion of the outer surface of a housing from a patient’s bone when the housing is positioned adjacent the patient’s bone prior to osseointegration, as recited in claim 1.

6. The Examiner suggests, with respect to claim 108, that functional language only requires that the prior art disclose structure capable of performing the function. *See* page 3, ¶7 of the outstanding office action. Applicant disagrees and notes that for the structure to be capable of performing the function, MPEP §2114 requires that the limitations at issue must be inherent in the prior art reference. That is, the structure must be inherently capable of performing such function.

7. Further, the MPEP, when addressing the issue of inherency specifically states in §2112 IV:

“the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). “To establish inherency, the extrinsic evidence ‘must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.’ ” *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted)” MPEP §2112 IV.

8. Thus, even assuming for the purposes of this response, that it might be possible for Berrang to perform the function of the structure recited in claim 1; the Federal Circuit has clearly stated that “Inherency... may not be established by probabilities or possibilities.” *In re Robertson* at 745. The Examiner must provide extrinsic evidence that makes it clear that the missing descriptive matter is necessarily present in Berrang. Applicant respectfully request that the Examiner cite in the Berrang specification or in any other prior art, evidence of a protuberance configured to osseointegrate with the patient’s bone without manual assistance, wherein the protuberance extends from the outer surface of the housing, the protuberance configured to separate at least a portion of the outer surface of the housing from the patient’s bone when the housing is positioned adjacent the patient’s bone prior to osseointegration, as recited in claim 1.

9. With respect to obviousness, the Supreme Court recognized in *KSR International Co. v. Teleflex Inc.*, that “rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some *articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.*” (*See KSR*, 127 S.Ct. at 1741 (citing *In re Kahn*, 441 F.3d 977, 988 (C.A.Fed. 2006); (emphasis added). Applicant submits that there is no such rational anywhere in the cited prior art regarding: 1) a protuberance configured to

osseointegrate with the patient's bone without manual assistance; or 2) a protuberance configured to separate at least a portion of the outer surface of a housing from the patient's bone when the housing is positioned adjacent the patient's bone prior to osseointegration. Therefore, any obviousness rejection based on Berrang would merely just include conclusory statements.

10. Applicant submits that Berrang fails to disclose or render claim 1 and therefore, claim 1 is allowable over the cited prior art.

Independent Claim 93

11. The Examiner does not specifically address the elements of independent claim 93; therefore, it must be assumed that the Examiner believes that Berrang discloses all of the method steps of this claim.

12. Applicant respectfully disagrees. To anticipate a claim, the reference must teach every element of the claim. MPEP §2131.01. Berrang clearly fails to disclose or render obvious each and every element of claim 93.

13. Independent method claim 93 recites a method for implanting an implantable device having a housing with an outer surface configured to prevent osseointegration of the housing with a patient's bone and at least one osseointegrating protuberance extending from the housing, the method comprising: forming a pocket on the patient's bone to receive the housing; positioning the housing in said pocket such that the at least one protuberance is in direct contact with the patient's bone; and allowing osseointegration of the at least one protuberance to occur in the absence of manual assistance. (emphasis added).

14. There is no disclosure in the Berrang specification of a method that allows titanium screws to osseointegrate in the absence of manual assistance. To meet this claim element, the Examiner must cite to disclosure in the specification of this specific method step being performed. Berrang merely states that a housing "can be conveniently ...attached to the underlying bone with...titanium screws." ¶[0022]. Such a statement does not disclose the osseointegration step of claim 93.

15. The Examiner may suggest that such a step is "inherent" in Berrang; however, that would be a misplaced contention. As noted above, the Examiner must cite extrinsic evidence that makes it clear that the missing descriptive matter is necessarily present. There is no such evidence in the record of this application.

16. Applicant notes that the term osseointegrate or any variation thereof does not even appear in the Berrang specification. Applicant fails to understand how a prior art reference can disclose each and every element of a claim, as required under 35 U.S.C. §102, when there is simply no discussion of the claimed subject matter.

17. Furthermore, Berrang does not render claim 93 obvious. Applicant submits that there is no articulated reasoning with some rational underpinning to support a legal conclusion of obviousness anywhere in the cited prior art regarding the osseointegration step, as required by the Supreme Court. *See KSR* at 988. Therefore, any obviousness rejection based on Berrang would merely just include conclusory statements.

18. Thus, Applicant submits that independent claim 93 is allowable over the cited prior art.

19. With respect to dependent claim 95, this claim is dependent from claim 93 and further recites positioning at least two protuberances to the patient's bone such that the implant axis is substantially orthogonal to the patient's bone and such that at least a portion of the housing outer surface is spaced from patient's bone before osseointegration occurs.

20. Berrang clearly fails to disclose or render obvious such a method step. Therefore, Applicant submit that dependent claim 95 is allowable over the cited prior art.

Independent Claim 108

21. With respect to independent claim 108, the Examiner states that the "limitation 'configured to be placed in direct contact with but not within the bone and further configured to gradually sink into the bone during osseointegration of said protuberance', is only functional language and only requires the capability to so perform." The Examiner further states that Berrang's "titanium screws are capable of being positioned adjacent the bone and are further capable of sinking into the bone during osseointegration." Pg. 3 of the Office Action.

22. Again Applicant submits that, even assuming for the purposes of this response, that it might be possible for Berrang to perform the function of the structure recited in claim 108; there is no evidence of such. Applicant respectfully requests that the Examiner cite where in the Berrang specification or any other prior art there is evidence that titanium screws are capable of being positioned adjacent the bone and are further capable of sinking into the bone during osseointegration.

23. Applicant submits that Berrang fails to disclose or render obvious such a structure; therefore, claim 108 is allowable over the cited prior art.
24. Claims 5-6, 21-23, 94-96, 101-103, 112 and 113 are rejected under 35 U.S.C. §103(a) as being unpatentable over Berrang in view of U.S. Patent No. 6,840,919 to Hakansson ("Hakansson").
25. Applicant submits that Hakansson fails to overcome the deficiencies of Berrang and therefore, each of these claims is allowable for at least the reasons discussed above.

Dependent claims

26. The dependent claims incorporate all the subject matter of their respective independent claims and add additional subject matter which makes them independently patentable over the art of record. Accordingly, Applicant respectfully asserts that the dependent claims are also allowable over the art of record.

Conclusion

27. In view of the foregoing, this application should be in condition for allowance. A notice to his effect is respectfully requested.
28. Applicant reserves the right to pursue any cancelled claims or other subject matter disclosed in this application in a continuation or divisional application, cancellations and amendments of above claims, therefore, are not to be construed as an admission regarding the patentability of any claims and Applicant reserves the right to pursue such claims in a continuation or divisional application.

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Respectfully submitted,

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